CD Horizon® Spinal System
510(k) Summary
February 2014

I.	**COMPANY:**	Medtronic Sofamor Danek USA, Inc 1800 Pyramid Place Memphis, Tennessee 38132
	CONTACT:	Gregory Maschek Regulatory Affairs Specialist Telephone: (901) 396-3133 Fax: (901) 346-9738
II.	**PROPRIETARY TRADE NAME:**	CD Horizon® Spinal System
III.	**COMMON OR USUAL NAME:**	Spinal Fixation Appliance, Spinal Fixation Orthosis
IV.	**CLASSIFICATION NAMES:**	Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050) Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060) Spondylolisthesis Spinal Fixation Orthosis (21 CFR 888.3070) Spinal Pedicle Fixation Orthosis (21 CFR 888.3070) Spinal Pedicle Fixation, For Degenerative Disc Disease Orthosis (21 CFR 888.3070) Adolescent Idiopathic Scoliosis Pedicle Screw Spinal System, (21 CFR 888.3070)
	CLASS:	III (Pre-Amendment)
V.	**PRODUCT CODE:**	KWP, KWQ, MNH, MNI, NKB, & OSH

VI. PRODUCT DESCRIPTION:

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples, and connecting components, as well as implant components from other Medtronic spinal systems which can be rigidly locked

into a variety of configurations with each construct being tailor-made for the individual case.

A subset of CD HORIZON® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws, CROSSLINK® Plates and connecting components. Similarly to the CD HORIZON® implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The purpose of this submission is to modify Medtronic's CD HORIZON® Spinal System to add additional components to the system, specifically, modified Side Loading/Closed Domino Connectors.

VII. INDICATIONS FOR USE:

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CDHORIZON® SPIRE™ Plate is a posterior, single level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis; trauma; and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

VIII. IDENTIFICATION OF LEGALLY MARKETED DEVICES USED TO CLAIM SUBSTANTIAL EQUIVALENCE:

The subject CD HORIZON® Spinal System indications, intended use, fundamental scientific technology, design features, sterilization, and materials are similar to other legally marketed devices, specifically Medtronic's CD HORIZON® Spinal System. These predicates include CD HORIZON® Spinal System K090390 (S.E. 05/15/2009) and CD HORIZON® Spinal System K101074 (S.E. 06/22/2010)

IX. SUMMARY OF THE TECHNILOGICAL CHRACTERISTICS:

The subject CD HORIZON® Spinal System has identical indications, intended use, fundamental scientific technology, materials, and similar design features as the previously FDA cleared predicates; CD HORIZON® Spinal System K090390 (S.E. 05/15/2009) and CD HORIZON® Spinal System K101074 (S.E. 06/22/2010). Like the predicate CD HORIZON® Spinal System domino connectors, the subject domino connectors are available in titanium alloy or stainless steel. The subject domino connectors are used for an offset/angled connection of two rods to extend a construct. Additionally, the sizes of the domino connectors are within the size range of the predicate domino connectors.

X. DISCUSSION OF NON-CLINICAL TESTING:

A risk analysis of the device modifications was completed in accordance with Medtronic design control procedures. The risk analysis, which included an engineering rationale, demonstrated that the subject CD HORIZON® Spinal System does not introduce new issues of safety or effectiveness. No additional non-clinical testing was performed.

XI. DISCUSSION OF CLINICAL TESTING:

No clinical testing was performed

XII. CONCLUSION:

A risk analysis was completed for the modifications to the subject devices. Based on the results and additional supporting documentation provided in this submission, the subject devices demonstrated substantial equivalence to the previously listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2014

Medtronic Sofamor Danek USA, Incorporated
Mr. Gregory Maschek
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K140449
Trade/Device Name: CD HORIZON® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: February 21, 2014
Received: February 24, 2014

Dear Mr. Maschek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140449

Device Name
CD HORIZON® Spinal System

Indications for Use *(Describe)*
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

James P. Bertram -S
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